

**Amendment and Response**

Applicant: Jack D. Lemmon

Serial No.: 10/688,718

Filed: October 17, 2003

Docket No.: M190.143.101

Title: PROSTHETIC HEART VALVE SIZER ASSEMBLY WITH FLEXIBLE SIZER BODY

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**REMARKS**

The following remarks are made in response to the Non-Final Office Action mailed February 8, 2006. In that Office Action, the Examiner reconsidered the previously-traversed withdrawal of claims 4-6, which is noted with appreciation. Newly presented claim 39 was deemed as being directed toward an invention that is independent or distinct from the invention originally claimed. The Examiner also objected to the specification as failing to provide proper antecedent basis for the claimed subject matter. Claims 1-6, 8-13, 15-21, and 25-28 were rejected under 35 U.S.C. §102(e) as being anticipated by, or in the alternative under 35 U.S.C. §103(a) as being obvious over, Johnson et al., U.S. Publication No. 2004/0024451 ("Johnson"). Claims 1-6, 8-13, 15-21, and 25-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lam et al., PCT Publication No. WO97/25003 ("Lam") in view of Love et al., U.S. Publication No. 2002/0020074 ("Love") and when necessary, further in view of Rhee, U.S. Patent No. 6,350,281 ("Rhee").

The Examiner's indication that claim 38 has been allowed and that claims 22-24, although objected to as being dependent upon a rejected claim, would be deemed allowable if re-written in independent form, is noted with appreciation.

With this Response, claim 1 has been amended, claim 39 canceled and claim 40 added. Claims 1-31, 38 and 40 remain pending in the application and are presented for consideration and allowance.

**Objection to Claim 39**

Pursuant to the Examiner's restriction, claim 39 has been canceled.

**Objection to the Specification**

Claim 1 has been amended to reflect that the outer ring defines an undulating, contoured axial end surface. Support for the language is found, for example in FIG. 8 and at page 8, line 23 – page 9, line 2. In this regard, it is affirmatively stated that the limitations of claim 1 do not preclude or require a circular outer circumference or an undulating, contoured outer

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circumference as otherwise identified in the Office Action; the embodiment of FIG. 3 is but one configuration in accordance with principles of the present invention. It is respectfully submitted that the objection to the specification has been traversed.

**35 U.S.C. §§102 and 103 Rejections**

With respect to the rejections of independent claims 1 and 20 as being anticipated by Johnson, it is respectfully noted at the outset that Johnson describes a prosthetic heart valve and not a flexible sizer body. For this reason alone, claims 1 and 20 are not anticipated by Johnson. To the contrary, the preamble of claims 1 and 20 recites a “flexible sizer body for evaluating a valve annulus to determine a size of a prosthetic heart valve to be sewn to the valve annulus during heart valve replacement surgery”. This recitation dictates a structural difference between the claimed invention and Johnson. That is to say, the framework – the teachings of the prior art – against which patentability is measured is not any and all devices related to heart valves, but instead sizer bodies for evaluating a heart valve annulus to determine a size of a prosthetic heart valve to be send to the valve annulus. MPEP §2111.02. Thus, Johnson cannot be viewed as teaching claims 1 and 20.

Further, it is respectfully submitted that Johnson does not anticipate the limitation of claim 1 of “a continuous outer ring characterized by the absence of a cloth cover.” Johnson describes a prosthetic heart valve 22; by its very nature, the prosthetic heart valve must be sutured to heart tissue at or adjacent the heart valve annulus to complete implantation thereof. To this end, and commensurate with conventional prosthetic heart valves, the prosthetic heart valve 22 includes a stent 24 forming stent posts 26 and a stent ring 30. The stent 24 is covered by a cloth cover, including the cover 32 covering the stent ring 30 and the covering 36 encompassing the stent posts 26. Johnson describes that the covering 36 is formed of a fabric material to which leaflets 28 are sutured. In this same manner, the cover 32 over the stent ring 30 is also configured for suturing; in particular, Johnson describes that the cover 32 serves as a suturing annulus or ring (Johnson, Para. 46). This indication of the cover 32 being of a cloth construction is further repeated at paragraph 68 where it is described that a line 50 is sewn or

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stitched through or into the cover 32. The illustrations of FIGS. 1 and 6A make clear that the covers 32 and 36 are identical and thus are both a cloth material. Because nothing in Johnson indicates that the described cover 32 is different from the covering 36 or otherwise different from conventional prosthetic heart valves of similar construction, it is respectfully submitted that in contrast to statements in the Office Action, Johnson does at least inherently teach that the cover 32 is cloth. For at least this additional reason, then, it is respectfully submitted that claims 1 and 20 are not anticipated by Johnson.

Claim 2-6, 8-13, and 15-19 depend from claim 1; and claims 21 and 25-28 depend from claim 20. For at least the reasons described above, then, it is respectfully submitted that claims 2-6, 8-13, 15-19, 21, and 25-28 are also not anticipated by Johnson. It is further noted that the Office Action does not identify the limitations of at least claims 10, 11, 13, and 19 in Johnson; it is respectfully submitted that at least these claims define further allowable subject matter over Johnson. Finally, to the extent Johnson is relied upon in formulating a rejection of any claims under 35 U.S.C. §103, it is respectfully noted that Johnson is not available art pursuant to §103(c). More particularly, Johnson and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. Assignment of Johnson to Medtronic, Inc. was recorded by the USPTO Assignment Division at Reel No. 014177, Frame No. 0115; assignment of the pending application to Medtronic, Inc. was recorded by the USPTO Assignment Division at Reel No. 014628, Frame No. 0461.

For at least the above reasons, it is respectfully submitted that the rejections of claims 1-6, 8-13, 15-21, and 25-28 under 35 U.S.C. §102 and §103 in view of Johnson have been traversed.

With respect to the rejection of claim 1 as being unpatentable over Lam in view of Love and Rhee, applicant respectfully disputes the asserted suggestion identified in the Office Action for modifying Lam in view of Love. The sizing obturator 10 of Lam is configured for insertion into an aortic valve annulus following performance of a valvulotomy to determine the correct size of a prosthetic valve to be surgically implanted therein (Lam, p. 1, ll. 2-7). The obturator 10

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includes a body 12 and a flange 18, with the body 12 defining a distal portion of the sizer 10. As shown in the various figures of Lam, the distal body 12 is a simple, continuous, right cylinder; in fact, Lam describes that a primary object of the invention is to provide a cylindrical body which may be inserted through the annulus (Lam, p. 3, ll. 33-36). The flange 18, on the other hand, has a larger diameter than the cylinder body 12, and is adapted to be complimentary in shape to the superior aspect of the aortic annulus to which the obturator 10 is placed during use. During use, Lam specifically describes that the aortic valve leaflets are first surgically removed (Lam, p. 10, ll. 33-37). Following the valvulotomy, the obturator 10 is inserted such that the cylinder body 12 passes downwardly through the surgically-prepared valve annulus with little resistance, followed by rotation of the obturator 10 to nest the larger diameter flange 18 against the valve annulus structure (Lam, p. 11, ll. 1-12). Thus, the cylinder body 12 serves to determine desired prosthetic valve mounting or annulus diameter, whereas the flange 18 serves to determine desired prosthetic valve sewing ring diameter (Lam, p. 9, ll. 5-17).

In contrast, Love relates to a measuring instrument used to measure the size and dimensions of heart valves as part of a heart valve reconstruction or replacement (Love, Para. 2). More particularly, the Love instrument is employed in connection with valve reconstruction, as opposed to replacement (Love, Para. 3). With this in mind, the Love measuring instrument of FIGS. 1 and 2 includes a circular sizing portion 1 and three curved legs 2. The sizing portion 1 is used to measure the diameter of the valve orifice (Love, Para. 18). The legs 2 are used to measure individual leaflet height (Love, Para. 20), and collectively define a diameter substantially equivalent to the diameter of the circular sizing portion 1 (Love, Para. 18). Thus, the Love measuring instrument is specifically configured for use in evaluating a heart valve anatomy in which the leaflets have not been surgically removed; the circular sizing portion 1 used to measure annulus diameter and the legs 2 used to measure leaflet height.

In light of the above, Lam and Love are configured for distinct applications, such that a requisite suggestion to modify Lam in view of Love does not exist. In particular, the Lam obturator 10 sizes a valve anatomy after removal of the leaflets, whereas the Love measuring device measures a valve anatomy that specifically includes the leaflets. Because the Lam device

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is used following a valvulotomy, Lam has no need for the legs 2 as taught by Love, as the legs 2 are configured and provided for the sole purpose of measuring leaflet height. With Lam, the leaflets have been removed, and thus cannot be measured. Pointedly, the cylinder body 12 of Lam is essentially the same as the circular sizing portion 1 of Love; both components are provided to measure annulus diameter. As such, one of skill would not view the legs 2 of Love as being a possible modification to the cylinder body 12 of Lam. To the contrary, the legs 2 of Love represent a component in addition to the circular sizing portion 1, and thus as a component in addition to the cylinder body 12 Lam. That is to say, the legs 2 cannot be viewed as a possible modification of the cylinder body 12 of Lam. Because the proposed modification would change the principle of operation of Lam, a requisite suggestion to combine does not exist. MPEP 2143.01 VI.

Even further, Love teaches that the legs 2 have a collective diameter equivalent to the diameter of the circular sizing portion 1. As such, modifying Lam in view of Love results in the modified cylinder body 12 having a diameter equivalent to that of the flange 18. With this construction, the modified Lam device would not be satisfactory for its intended use. Namely, because the modified cylinder body 12 and the flange 18 have the same diameter, it would be essentially impossible to “seat” the flange 18 against the valve annulus while simultaneously having the cylinder body 12 passed through the valve annulus. Either the cylinder body 12 would not pass through the valve annulus (where the diameter of the cylinder body 12/flange 18 was larger than that of the valve annulus), or the cylinder body 12/flange 18 would pass through the valve annulus with the flange 18 not seating against the valve annulus (where the diameter of cylinder body 12/flange 18 was smaller than that of the valve annulus). Because seating of the flange 18 against the valve annulus along with passage of the cylinder body 12 through the valve annulus is a feature required by Lam (Lam, p. 9, ll. 1-17), the proposed modification would render Lam unsatisfactory for its intended purpose. This, in turn, dictates that a requisite motivation to modify Lam in view of Love does not exist. MPEP 2143.01 V.

For at least the above reasons, it is respectfully submitted that claim 1 is not made obvious by Lam in view of Love; a *prima facie* case of obviousness cannot be established.

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Claims 2-6, 8-13, and 15-19 depend from claim 1, and thus for at least these same reasons, are also allowable over Lam in view of Love (or further in view of Rhee). As such, it is respectfully requested the rejections of claims 1-6, 8-13 and 15-19 based upon Lam in view of Love and Rhee be withdrawn.

Similar distinctions exist with respect to claim 20. For example, a requisite suggestion to modify Lam in view of Love does not exist, such that at least the annular wall forming a plurality of extremities defines allowable subject matter. In addition, it is respectfully submitted that Lam does not teach or suggest a sizer assembly configuration in which a length between a second end of a handle and the extremities of the sizer body are less than the length between the handle second end and the sizer body outer ring as otherwise recited in claim 20. The Office Action identifies the flange 18 of Lam as being the claimed outer ring, and the cylinder body 14 (or 12) of Lam as providing the extremities (as modified by Love). With this in mind, FIG. 7A of Lam clearly illustrates that the obturator 10 is arranged relative to the handle 40 such that the flange 18 is closer to the handle 40 end opposite the obturator 10 as compared to the cylinder body 12. In other words, Lam teaches the direct opposite of claim 20; the length between the extremities (as otherwise formed by the modified cylinder body 12) and the handle second end is greater than the length between the outer ring/flange 18 and the handle second end. Love and Rhee are similarly limited. For at least these reasons, then, it is respectfully submitted that claim 20, as well as all claims depending therefrom, are allowable over Lam in view of Love and Rhee. Withdrawal of the rejections of claims 20, 21, and 25-28 is respectfully requested.

As a point of clarification, it is noted that the Office Action does not provide a specific rejection of claim 30. To the extent the Examiner intended to rely upon Lam in view of Love and/or Rhee in rejecting claim 30, claim 30 depends from claim 20 and thus for at least the above reasons, is also allowable over Lam in view of Love and Rhee.

**Newly Present Claim 40**

Newly presented claim 40 depends from claim 1 and thus for at least the reasons described above, is allowable over the cited references. Claim 40 further recites that the outer

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ring and the annular wall have the same exterior material. Support for this language is found, for example, at page 10, lines 20-21; FIG. 2B. Relative to the rejection of claim 1 as being anticipated by Johnson, to the extent the cover 32 is viewed as being different from the cloth covering 36, the limitations of claim 40 are not taught. Conversely, to the extent the cover 32 is viewed as being the same as the cloth covering 26, the claim 1 is not anticipated.

**CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 1-31, 38, and 40 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-31, 38, and 40 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

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Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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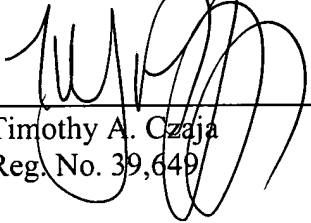
Respectfully submitted,

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By his attorneys,

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CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450 on this 9th day of May, 2006.

By: 

Name: Timothy A. Czaja